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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,378	02/23/2004	Brent R. Constantz	CORA-008CON2	6518

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EXAMINER	
FRISTOE JR, JOHN K	

ART UNIT	PAPER NUMBER
3751	

DATE MAILED: 07/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/785,378	CONSTANTZ ET AL.	
	Examiner	Art Unit	
	John K. Fristoe Jr.	3751	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 5/26/2004 is acknowledged by the examiner.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the examiner if claim 18 is referring back to claim 1 or claim 11.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-9, 11-17, and 19-22 are rejected under the judicially created doctrine of double patenting over claims 1, 1, 2, 3, 5, 4, and 6-19, respectively, of U. S. Patent No. 6,719,747 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 1, 2, 3, 5, 4, and 6-19 of U.S. Pat. No. 6,719,747 "anticipate" Application claims 1-9, 11-17, and 19-22, respectively. Accordingly, Application claims 1-9, 11-17, and 19-22 are not patentably distinct from Patent claims 1, 1, 2, 3, 5, 4, and 6-19, respectively.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Here Patent claim 1 requires:

A catheter device consisting essentially of at its distal end;

- A proton generating means;
- A vascular site flushing means comprising separate fluid introduction and aspiration elements; and said catheter device generating protons in a manner sufficient to provide for a subphysiological pH in the vascular site.

While application claim 1 requires:

A catheter device containing a distal end;

- A proton generating means; and
- A vascular site flushing means.

Thus it is apparent that the more specific patent claim 1 encompasses Application claim 1. Following the rationale in *In re Goodman* cited in the preceding paragraph, where Applicant has once been granted a patent containing a claim for the specific or narrower invention, Applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer. Note that since Application claim 1 is anticipated by Patent claim 1 and since anticipation is the epitome of obviousness, then Application claim 1 is obvious over Patent claim 1.

Here Patent claim 6 requires:

A catheter device consisting essentially of at its distal end;

- A proton generating means comprising an anode and a cathode;
- A fluid introduction means; and
- An aspiration means that is separate from said fluid introduction means.

While Application claim 7 requires:

A catheter device comprising at its distal end;

- A proton generating means comprising an anode and a cathode;
- A fluid introduction means; and
- An aspiration means.

Thus it is apparent that the more specific patent claim 6 encompasses Application claim 7. Following the rationale in *In re Goodman* cited in the preceding paragraph, where Applicant has once been granted a patent containing a claim for the specific or narrower invention, Applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer. Note that since Application claim 7 is anticipated by Patent claim 6 and since anticipation is the epitome of obviousness, then Application claim 7 is obvious over Patent claim 6.

Here Patent claim 9 requires:

A method of enhancing fluid flow through a vascular site occupied by a vascular occlusion, said method comprising;

- Generating protons from water in said vascular site using a device according to claim 1 in a manner sufficient to provide for subphysiological pH in said vascular site; and
- Maintaining said subphysiological pH in said vascular site for a period of time sufficient for fluid flow to be enhanced through said vascular site; and
- Whereby fluid flow is enhanced through said vascular site.

While Application claim 11 requires:

A method of enhancing fluid flow through a vascular site occupied by a vascular occlusion, said method comprising;

- Generating protons from water in said vascular site in a manner sufficient to provide for subphysiological pH in said vascular site; and
- Maintaining said subphysiological pH in said vascular site for a period of time sufficient for fluid flow to be enhanced through said vascular site;
- Whereby fluid flow is enhanced through said vascular site.

Thus it is apparent that the more specific patent claim 9 encompasses Application claim 11. Following the rationale in *In re Goodman* cited in the preceding paragraph, where Applicant has once been granted a patent containing a claim for the specific or narrower invention, Applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer. Note that since Application claim 11 is anticipated by Patent claim 9 and since anticipation is the epitome of obviousness, then Application claim 11 is obvious over Patent claim 9.

6. Similarly, claims 2-6, 8, 9, 12-17, and 19-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5, 4, 7, 8, and 10-19, respectively, for the same reason set forth above.

7. Claims 11-17 are rejected under the judicially created doctrine of double patenting over claims 1-7, respectively, of U. S. Patent No. 6,540,733 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. Although the conflicting

claims are not identical, they are not patentably distinct from each other because claims 1-7 of U.S. Pat. No. 6,540,733 "anticipate" Application claims 11-17, respectively. Accordingly, Application claims 11-17 are not patentably distinct from Patent claims 1-7, respectively.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Here Patent claim 1 requires:

A method of enhancing fluid flow through a vascular site occupied by a vascular occlusion, said method comprising;

- Positioning a proton generating electrode at said vascular site;
- Generating protons from water in said vascular site using said proton generating element in a manner sufficient to provide for subphysiological pH in said vascular site; and
- Maintaining said subphysiological pH in said vascular site for a period of time sufficient for fluid flow is enhanced through said vascular site.

While Application claim 11 requires:

A method of enhancing fluid flow through a vascular site occupied by a vascular occlusion, said method comprising;

- Generating protons from water in said vascular site in a manner sufficient to provide for subphysiological pH in said vascular site; and

- Maintaining said subphysiological pH in said vascular site for a period of time sufficient for fluid flow to be enhanced through said vascular site;
- Whereby fluid flow is enhanced through said vascular site.

Thus it is apparent that the more specific patent claim 1 encompasses Application claim 11. Following the rationale in *In re Goodman* cited in the preceding paragraph, where Applicant has once been granted a patent containing a claim for the specific or narrower invention, Applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer. Note that since Application claim 11 is anticipated by Patent claim 1 and since anticipation is the epitome of obviousness, then Application claim 11 is obvious over Patent claim 1.

Similarly, claims 12-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 110-15, respectively, for the same reason set forth above.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-9 and 19-22 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 6,183,469 (Thapliyal et al.). Thapliyal et al. disclose a catheter device comprising a

distal end (figure 8B), a proton generating means that is an electrode assembly (72 and 74), a vascular site flushing means (126, 128, 130, and 132), a fluid introduction means (126 and 128), a fluid aspiration means (130 and 132), an anode (63), a cathode (65), two distinct elements that are moveable relative to each other (62 and 170), means for applying electrical potential (80), a manifold (114), an aqueous fluid reservoir (100), a source of negative pressure (97), a guidewire (col. 18, lines 47-53), and wherein the catheter device is a kit (figure 3).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,183,469 (Thapliyal et al.) in view of U.S. Pat. No. 3,707,960 (Freed). Thapliyal et al. disclose a catheter device comprising a distal end (figure 8B), a proton generating means that is an electrode assembly (72 and 74), a vascular site flushing means (126, 128, 130, and 132), a fluid introduction means (126 and 128), a fluid aspiration means (130 and 132), an anode (63), a cathode (65), two distinct elements that are moveable relative to each other (62 and 170), means for applying electrical potential (80), a manifold (114), an aqueous fluid reservoir (100), a source of negative pressure (97), a guidewire (col. 18, lines 47-53), and wherein the catheter device is a kit (figure 3) but lacks a vascular occlusion means. Freed discloses a catheter device comprising a vascular occlusion means (16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the catheter device of Thapliyal et al. by adding a

vascular occlusion means to the catheter device as taught by Freed in order to inhibit the flow of blood to the surgical site which may inhibit the surgical procedure.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John K. Fristoe Jr. whose telephone number is (571) 272-4926. The examiner can normally be reached on Monday-Friday, 7: 00 a.m-4: 30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine R. Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John K. Fristoe Jr.
Examiner
Art Unit 3751

JKF

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7/8/05